

The Denosumab Trial: Pilot Study of Denosumab in BRCA1/2 Mutation Carriers Scheduling Risk-Reducing Salpingo-oophorectomy (Removal of Ovaries and Fallopian Tubes)

Why is this study being done?

The purpose of this study is to see if taking the study drug, Denosumab, causes any changes in the fallopian tubes of women that may reduce the risk of developing ovarian cancer. The study will focus on women who have *BRCA1/2* mutations and are having a risk-reducing salpingo-oophorectomy (RRSO).

Denosumab is a medication approved by the US Food and Drug Administration for osteoporosis (weakening of the bones) and to prevent the spread of some cancers to bone. It is being studied for *BRCA1/2* cancer prevention based on laboratory research and human studies. It is given by injection.

Who can participate in this study?

You may be eligible for this study if you:

- Are an adult, premenopausal woman;
- Have a *BRCA1* or *BRCA2* mutation;
- Are planning to have a preventive removal of the ovaries and fallopian tubes;
- Have never had ovarian cancer

What will happen if you join the study?

There are 2 study groups: you have a 50-50 chance of being in either. One group will receive injections of Denosumab for 3 to 4 months before their surgeries; one group will not. You will also be asked to:

- Have blood drawn for testing and research;
- Allow the study team to access to your medical records;
- Take Calcium and Vitamin D supplements daily for 6 months;
- Return to the clinic 9 months and 12 months after you start the study for evaluation;
- Have phone calls with the study team regularly to check on progress and talk about symptoms

How long is the study?

If you agree, you will be on the study for a total of one year. During that time, you will take Calcium and Vitamin D supplements for 6 months and may receive monthly injections of Denosumab for 3 to 4 months before your surgery. The final study visit will happen about 12 months after joining the study.

How do I get more information?

If you, a friend, or a family member wish to participate in or learn more about the study, please contact:

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